K080935

AUG - 6 2008

510 (k) Summary for the Sonix MDP Ultrasound Scanner

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Devices Act of 1990 revisions to 21 CFR, Part 807.92, Content and format of a 510(k) summary.

1.0 Submitter Information

1.1 Submitter

Ultrasonix Medical Corporation
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(t) 604-437-9500
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1.2 Contact

Chas Yu
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1.3 Date Prepared

April 1, 2008

2.0 Device Name

2.1 Common Name

Ultrasound Imaging System

2.2 Proprietary Name

Sonix MDP Ultrasound Scanner

2.3 Classification Name

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

2.4 Classification

Class II

2.5 Predicate Device:

SonoSite MicroMaxx High Resolution Ultrsound System (K053069)
Ultrasonix Ergosonix 500 Ultrasound Scanner (K042326)
SONIX Ultrasound Scanner (K061827)
Philips HD 11 Diagnostic Ultrasound System (K062247)
GE Logiq P5 and A5 (K060993)

2.6 Reason for submission:

Name change request

N/A

New product clearance for:

SONIX MDP Ultrasound Scanner and Transducers:	L14-5/38 C5-2/60 EC9-5/10 SA4-2/24

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Chas Yu
Quality Assurance Manager
Ultrasonix Medical Corporation
130-4311 Viking Way
Richmond, BC, V6V 2K9
CANADA

AUG - 6 2008

Re: K080935
Trade/Device Name: SONIX MDP Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 10, 2008
Received: June 19, 2008

Dear Mr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONIX MDP Ultrasound System, as described in your premarket notification:

Transducer Model Number

SA/24mm Phased Array 2.8 MHz
C5-2/60 Convex 3.2 MHz 60mm Radius
EC9-5/10 Microconvex Endocavity 6.6 MHz 10mm Radius
L14-5/38 Linear 8 MHz 38mm

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all

the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K080935

Device Name: SONIX MDP Ultrasound System

Indications For Use:

The SONIX MDP Ultrasound System is intended for the following applications: Ophthalmic, Abdominal, Cardiac, Intraoperative (specific), Intraoperative Neurological, Fetal, Pediatric, Small Parts, Neonatal/ Adult Cephalic, OB/GYN, Transesophageal, Transrectal, Transvaginal, Peripheral Vascular, Musculoskeletal conventional, Musculoskeletal superficial, Pelvic, Nerve Block, Vascular Access.

The system also provides the ability to measure anatomical structures {fetal, abdominal, pediatric, small organ, cardiac, transrectal, transvaginal, peripheral vessel, musculoskeletal} and provides calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

The SONIX MDP Ultrasound System indication(s) for use are the same as the predicate devices. Please see attached IFU comparison chart between SONIX MDP and the predicate devices.

The ultrasound plateform is similar to the predicate devices in terms of operation.
A transducer is applied to the patient and the system generates ultrasound waves then transmit the wave into human body. The system then receives echoes back from human body, processes them to yield an image on a display.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080935

ULTRASOUND INDICATIONS FOR USE TABLES

SONIX MDP Ultrasound Scanner – Diagnostic Ultrasound Indications for Use Form

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative Neurological		N	N	N		N	N	N	N (*1)	N (*2)
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal		N	N	N		N	N	N	N (*1)	N (*2)
Transrectal		N	N	N		N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N		N	N	N	N (*1)	N (*2)
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)										

N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Directional Power Doppler (DPD), Imaging for guidance of biopsy
*3. Imaging for guidance of nerve block injections
*4. Imaging for guidance of central or peripheral lines.

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Diagnostic ULTRASOUND INDICATIONS FOR USE Form
SA/24mm phased array 2.8 MHz transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		N	N	N	N	N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N	N	N	N	N	N (*1)	N (*2)
Small Organ (specify)										
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N	N	N	N	N	N (*1)	N (*2)
Cardiac		N	N	N	N	N	N	N	N (*1)	N (*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = **N**ew indication; **P** = **P**reviously cleared

Additional Comments:

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Directional Power Doppler (DPD)

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Diagnostic ULTRASOUND INDICATIONS FOR USE Form
C5-2/60 convex 3.2 MHz 60mm radius transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Directional Power Doppler (DPD), Imaging for guidance of biopsy

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Diagnostic ULTRASOUND INDICATIONS FOR USE Form
EC9-5/10 microconvex endocavity 6.6 MHz 10mm radius transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N	N		N	N	N	N (*1)	N (*2)
Transvaginal		N	N	N		N	N	N	N (*1)	N (*2)
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Vascular Access										
Nerve Block										
Other (specify)										

N = New indication; P = Previously cleared

Additional Comments:

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Directional Power Doppler (DPD), Imaging for guidance of biopsy

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Diagnostic ULTRASOUND INDICATIONS FOR USE Form
L14-5/38 linear 8 MHz 38mm transducer

Intended use:

Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		N	N	N		N	N	N	N (*1)	N (*2)
Abdominal		N	N	N		N	N	N	N (*1)	N (*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N	N		N	N	N	N (*1)	N (*2)
Small Organ (specify)		N	N	N		N	N	N	N (*1)	N (*2)
Neonatal Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Adult Cephalic		N	N	N		N	N	N	N (*1)	N (*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N	N	N	N (*1)	N (*2)
Laparoscopic										
MSK Conventional		N	N	N		N	N	N	N (*1)	N (*2)
MSK Superficial		N	N	N		N	N	N	N (*1)	N (*2)
Vascular Access		N	N	N		N	N	N	N (*1)	N (*2, *4)
Nerve Block		N	N	N		N	N	N	N (*1)	N (*2, *3)
Other (specify)										

N = New indication; P = Previously cleared

Additional Comments:

Small Organ: Breast, Thyroid, Testicle

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Directional Power Doppler (DPD), Imaging for guidance of biopsy
*3. Imaging for guidance of nerve block injections
*4. Imaging for guidance of central or peripheral lines.

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